



Participant ID: _____	Pin #: _____
Discovery Site: _____	Clinical Center: _____
CRF Date: ____/____/____	Visit #: _____

**MAPP Phase II Eligibility Confirmation for Control Participants**

Research Coordinator completes at **Month 0 and Month 6 Screening/Deep Phenotyping Clinic Contacts.**

1. Control Participant has signed and dated the appropriate Informed Consent document and has agreed to participate in <b>ALL</b> required <b>Controls Protocol</b> procedures (including <b>Biospecimen collections, MAPP Pelvic Exam, Neuroimaging, and Quantitative Sensory Testing</b> ).	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
a. If <b>Yes</b> , record date the form was signed	____/____/____	
b. Did the Control Participant give permission for use of DNA for genetics studies? (Answer to 1b <b>MUST</b> be <b>Yes</b> for Participant to be eligible.)	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
2. Participant gender:	<input type="checkbox"/> <sub>1</sub> Male	<input type="checkbox"/> <sub>2</sub> Female
3. Participant is ≥ 18 years of age.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
4. Participant is able to speak, read, and understand English.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No

**Inclusion Criteria**

5. Participant reports a response of <b>“0” (zero)</b> on the pain, pressure or discomfort scale ( <b>SYM-Q</b> , Question #1).	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No	<input type="checkbox"/> <sub>99</sub> N/A
6. Participant reports no chronic pain in the pelvic or bladder region, and reports <b>no</b> chronic pain in <b>any other body regions</b> .	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No	<input type="checkbox"/> <sub>99</sub> N/A
7. Participant reports no urological symptoms that have been evaluated, but are still present.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No	<input type="checkbox"/> <sub>99</sub> N/A

**ALL INCLUSION CRITERIA RESPONSES ABOVE MUST BE “YES” FOR THE CONTROL PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE MAPP CONTROLS STUDY.**

**Trans-MAPP Exclusion Criteria**

8. Participant has an on-going symptomatic urethral stricture.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
9. Participant has an on-going neurological disease or disorder affecting the bladder or bowel fistula.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
10. Participant has a history of cystitis caused by tuberculosis, radiation therapy or Cytosan/cyclophosphamide therapy.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
11. Participant has augmentation cystoplasty or cystectomy.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
12. Participant has an active autoimmune or infectious disorder (such as Crohn’s Disease or Ulcerative Colitis, Lupus, Rheumatoid Arthritis, Multiple Sclerosis, or HIV).	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
13. Participant has a history of cancer (with the exception of skin cancer).	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
14. Participant has current major psychiatric disorder or other psychiatric or medical issues that would interfere with study participation (e.g. dementia, psychosis, upcoming major surgery, etc).	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No
15. Participant has severe cardiac, pulmonary, renal, or hepatic disease that in the judgment of the study physician would preclude participation in this study.	<input type="checkbox"/> <sub>1</sub> Yes	<input type="checkbox"/> <sub>0</sub> No

**ALL TRANS-MAPP EXCLUSION CRITERIA RESPONSES MUST BE “NO” FOR THE CONTROL PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE MAPP II CONTROLS STUDY.**



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**Exclusion Criteria – Treatment and history**

- 16. Participant has had definitive treatment for acute epididymitis, urethritis, vaginitis. <sub>1</sub> Yes <sub>0</sub> No
- 17. Participant has history of unevaluated hematuria. <sub>1</sub> Yes <sub>0</sub> No
- 18. Participant has had a cystoscopy with hydrodistention or kenalog injection. <sub>1</sub> Yes <sub>0</sub> No

**ALL TREATMENT AND HISTORY EXCLUSION CRITERIA RESPONSES MUST BE “NO” FOR THE CONTROL PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE MAPPII CONTROLS STUDY.**

**Exclusion Criteria for Males ONLY, (Please record 99 – N/A for Females.)**

- 19. Male Participant diagnosed with unilateral orchalgia, without pelvic symptoms. <sub>1</sub> Yes <sub>0</sub> No <sub>99</sub> N/A
- 20. Male Participant has a history of transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), balloon dilation, prostate cryo-surgery, or laser procedure. <sub>1</sub> Yes <sub>0</sub> No <sub>99</sub> N/A
- 21. Male Participant has had a prostate biopsy or Transurethral Resection of the Prostate (TURP) within the last three months. <sub>1</sub> Yes <sub>0</sub> No <sub>99</sub> N/A

**Specimen Exclusion Criteria – Urine test results**

**\*Please note, the following section requires that a urine specimen be collected from the Participant in order to assess eligibility via the following procedures (check each box to confirm specimen collected and procedure done):**

Male and Female Participants:

- Urine dipstick
- Urine culture (Must be documented on Urine Culture Result for Control Pts. – UCR\_CON form)

Female Participants:

- Pregnancy Test

- 22. Participant has an abnormal dipstick urinalysis, indicating abnormal levels of nitrites and/or occult blood. <sub>1</sub> Yes <sub>0</sub> No

**Question #23 is an Exclusion Criterion for females of childbearing potential ONLY.**

**(Please record 99 - N/A for males and females who are surgically sterile or postmenopausal.)**

- 23. Female participant has a positive urine pregnancy test. <sub>1</sub> Yes <sub>0</sub> No <sub>99</sub> N/A  
(Must be excluded if positive urine pregnancy test.)



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**Fatigue Symptom Eligibility Criteria**

If the Control Participant has had any of these symptoms for at least **three (3) months in the past year**, please mark the appropriate box.

- |  |   |  |
|--|---|--|
| 24. Persistent fatigue not relieved with rest.           | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No |
| 25. Extreme fatigue following exercise or mild exertion. | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No |
| 26. Impaired memory, concentration or attention.         | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>0</sub> No |

**ALL RESPONSES FOR FATIGUE/IMPAIRMENT SYMPTOMS LISTED ABOVE  
MUST BE "NO" FOR THE CONTROL PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE MAPPII CONTROLS STUDY.**

27. Did the participant meet all eligibility criteria at this visit? <sub>1</sub> Yes   <sub>0</sub> No

28. Research Coordinator ID \_\_\_\_\_ (4-digit ID)